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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 067,436	02 05 2002	Matthew R. Martin	BIO-3.2.019-4215	7565

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EXAMINER

HUGHES, JAMES P

ART UNIT	PAPER NUMBER
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2881

DATE MAILED: 08 21 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,436

Applicant(s)

MARTIN ET AL.

Examiner

James P. Hughes

Art Unit

2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the application filed on Feb. 5, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 1-4 and 6-8 are objected to for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim language of “one” and “other” referring to individual parts of the pig (lines 7 and 8 of Claim 1), the complementary engaging elements (lines 9-13), and identifying between multiple options and relationships – such as “one of” in line 10 and “each other” in line 14 of Claim 1 – is highly confusing.

Additionally, the phrasing also leads to internal inconsistencies. For example, if an attempt is made to clarify the elements discussed by graphing – the first – for “one” (line 7 of Claim 1) and – the second – for “other” (line 8, of Claim 1); Claim 1 internally contradicts itself. Claim 1 recites “... [the first] of pig sections being moved away from the [second]...” (emphasis added) (lines 7-8), and later “... separation of the two pig section from each other in response to moving the [second] of the two pig sections away from the [first]...” (emphasis added) (lines 14-15). While this contradiction is technically possible due to changing reference frames of observation, it is self-contradictory. The claim language confusion is found in Claims 1-8. Appropriate action is required.

Claims 5 and 8 are objected to because of the following informalities. Claim 5 is missing a preposition such as “to” between the words “adjacent” (line 2) and “the” (line 3). Claim 8 is missing a preposition such as “to” between the words “adjacent” and “the” (line 3). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (5,672,883). The following rejections apply to the Office's best interpretation of the claims in light of the objections in section 1 above. Reich (5,672,883) teaches a radiopharmaceutical pig (10) comprising; a top (20) and bottom (22) pig sections configured to accommodate and enclose radiopharmaceuticals while the two sections are engaged. The two pig sections (20, 22) are configured to separate from each other in response to one of the pig sections (20) being moved away from the other (22). (Fig. 1 and Col. 5, ll. 59 – Col. 6, ll. 67, for example)

The radiopharmaceutical pig (10) also comprises two complementary engaging elements, the first (30) has internal mating threads and is integrally attached to the top (20) pig section; and the second (34) has external mating threads (36) and is integrally attached to the bottom (22) pig section. Each of the elements (30,34) are configured to hold the other stationary when they are engaged and permit separation of the two pig sections (20,22). (Fig. 1 and Col. 5, ll. 59 – Col. 6, ll. 67, for example)

However, Reich does not explicitly teach the pig sections configured in a manner to allow separation without the user needing to manually grasp one of the two pig sections.

Since it is commonly well known in the art that expedient removal of radiopharmaceuticals from pigs, and reduced exposure to operators is advantageous, it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the pig of Reich for one-handed operation. This could be accomplished in numerous ways. One apparatus and method would be to increase the weight of the lower (22) portion of the pig so that it would not tip over when an angular force was applied to the upper (20) portion for its removal using one hand. Reich teaches that the pigs are heavy due to internal radiological shielding (Col. 6, ll. 19-28), thus it would have been obvious to design a pig such that the lower portion has the necessary mass.

Another apparatus and method that would have been obvious to one of ordinary skill in the art at the time of the invention would have been to remove the upper (20) portion of the pig while it braced against one of numerous well-known support structures – such as a shipping container, a retention brace, an L-block radiation shield, or a counter top. Reich teaches the use of well-known shipping containers such as an “ammo can”. (Col. 10, ll. 53, for example)

Regarding Claim 2, individually, and together, the two complementary configurations comprise a multiple-sided recess or indentation – formed by the anti-roll ridges (40) on each element (34,36). (Fig. 1 and Col. 6, ll. 19-34)

Regarding Claims 5 and 9, Reich teaches that the top (20) and bottom (22) pig sections have tapered walls (Col. 8, ll. 1-15), the pig sections are not explicitly taught to have end portions whose thickness is greater than that of portions of sidewalls adjacent to the end portions. However, since it is well known in the art that lead shield of the pig is thinner along its side wall

close to where the two sections joining than at its ends, as disclosed by applicant (Paragraph 6, ll. 6-7); this type of structure would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zhu et al. (5,927,352) teaches a radiopharmaceutical pig (16) device comprising, two pig sections, "one" – upper portion – (72) and the "other" – cap – (76), that are configured to accommodate and enclose radiopharmaceutical contents when the two are engaged. The two sections are configured to separate from each other in response to the "one" (72) being moved away from the "other" (76) when the "other" (76) is removed. Additionally, there are two complementary engaging elements; the first – the inside of receptacle for the cap – is integrally formed with the "one" (72) section of the pig (16) and may be held stationary (the "one" (72) may be held stationary). The second complementary engaging element – the inside of the cap, which mates, with the cap receptacle of (72) – is integrally formed with one of [specifically, the "other" – cap – (76)]. While the two engagement elements permit the separation of two pig section away from each other.

Additionally, there is not need to manually grasp the "other" (72) pig section to effect separation as the pig (16) is supported by a heavy counter weight (Col. 5, ll. 50-60) and the need to grasp the "other" (72) pig section would slow down the radiopharmaceutical removal process, which the described invention is attempting to expedite (Col. 3, ll. 48-55).

Art Unit: 2881

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James P. Hughes whose telephone number is (703) 305-5675. The examiner can normally be reached on Monday - Friday 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on (703) 308-4116. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1782.

James P. Hughes
Examiner
Art Unit 2881

JH

August 9, 2003

JOHN R. LEE
SUPERVISORY PATENT EXAMINER
AUG 12 2003